UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

DAVID BAXTER, Plaintiff, v. MBA GROUP INSURANCE TRUST HEALTH AND WELFARE PLAN, et al., Defendants.	C12-1548 TSZ ORDER

THIS MATTER comes before the Court on the Parties' cross motions for summary judgment, docket nos. 14 and 18. The Court has reviewed the motions, opposition, and replies, and all pleadings related thereto, and now enters the following Order.

I. Background

Plaintiff David Baxter was diagnosed with early stage prostate cancer in September 2011. Complaint at ¶ 3; Administrative Record ("AR") at 139. Plaintiff was 51 years old and otherwise in good health at the time of diagnosis. AR at 139. His doctors classified his cancer as intermediate-risk. Id. at 23-24. He was a participant in

the "MBA Group Insurance Trust Health and Welfare Plan" (the "Plan"), an employee welfare benefit plan governed by the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1002(1). Complaint at ¶¶ 4-7. The Plan is underwritten and administered by Defendant Regence Blueshield ("Regence"). Id.

Following consultation with several specialists, Plaintiff determined that his preferred course of treatment was a form of radiation therapy called "proton therapy." Id. at ¶ 3. In contrast to more commonly used forms of radiation therapy that are delivered with x-rays, including conformal radiation therapy (CRT) and intensity-modulated radiation therapy (IMRT), proton therapy delivers radiation with proton beams. Rossi Decl. at 16-18, docket no. 16. Plaintiff concluded that proton therapy treatment would be the best option for controlling his cancer and preserving his quality of life. Complaint at ¶ 3. Plaintiff requested preauthorization for proton therapy from Regence. Id.; AR at 18.

Regence denied coverage on November 21, 2011. AR at 7. It concluded that proton therapy was not a "medically necessary" treatment under the relevant Plan language and Regence's Medical Policy 49. Id. at 7-9; Complaint at ¶ 3. Specifically, Regence stated:

> [W]e are unable to authorize the above service(s) because charged-particle irradiation with proton beams is considered not medically necessary in patients with clinically localized prostate cancer because the clinical outcomes with this treatment have not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT) or conformal radiation therapy. This request does not meet Regence Medical Policy [49].

AR at 7. Regence Medical Policy 49 provides, in relevant part:

> Charged-particle irradiation with proton beams is considered not medically necessary in patients with clinically localized prostate cancer because the clinical outcomes with this treatment have not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT) or conformal radiation therapy. Charged-particle irradiation with proton beams is more costly than other alternatives for treatment, and is therefore not medically necessary.

Id. at 82.

Plaintiff appealed the denial of coverage, arguing that proton therapy is clinically superior to IMRT and therefore, meets the Plan's definition of medically necessary treatment. Complaint at ¶ 36; AR at 32-64. Plaintiff also argued that Regence did not meet its burden to demonstrate that proton therapy is more costly than IMRT. Id. Plaintiff attached to his appeal letters of support from Dr. Grover, his treating physician at the Loma Linda University Medical Center facility where Plaintiff received proton therapy treatment, and from Dr. Laramore, a radiation oncologist and Chair of the Department of Radiation Oncology at the University of Washington Medical Center. AR at 66-73.

Regence referred the appeal for an independent medical review, AR at 26-30, and again denied coverage in February 2012, concluding that:

> We have decided the original denial was appropriate. As a result, we regret to inform you that your appeal has been denied. The rationale for this decision follows: As per our medical policy and National Comprehensive Cancer Network guidelines, proton beam therapy has not been proven better, or to have significantly fewer side effects, than intensity modulated radiation therapy (IMRT), brachytherapy, or 3D conformal radiation therapy (CRT). The reviewing physician notes that at the 2012 American Society of Clinical Oncology (ASCO) Genitourinary meeting, a study was presented comparing IMRT, 3D CRT, and proton therapy for prostate cancer using the Medicare SEER database from 2000 to 2009. The study showed that proton therapy was not associated with superior outcomes to

> IMRT, and that protons were associated with increased gastrointestinal toxicity.

Id. at 102 (emphasis added).

Plaintiff appealed a second time. Complaint at ¶ 38; AR 147-69. In his second appeal, Plaintiff informed Regence that he had completed proton therapy and had turned to family and friends to cover the cost of treatment. AR at 167. Regence again denied coverage. Id. at 519. In its denial letter, Regence stated:

> Our records indicate that your group coverage has been terminated effective August 1, 2012, following termination of your employment. Because you are requesting benefit consideration for future services on a closed account, your appeal has been declined.

Id.

Plaintiff commenced the present action in September 2012 under ERISA, 29 U.S.C. § 1132(a)(1)(B), which allows a plan participant or beneficiary to sue to "recover benefits due to him under the terms of the plan." He alleges that the Plan provides coverage for medically necessary treatment; that proton therapy was medically necessary in his case; and that Regence, both initially and following an administrative appeal, wrongfully denied coverage under the Plan. Plaintiff seeks reimbursement for the cost of the proton therapy, specific performance, costs and attorney fees. Complaint at ¶¶ 46-48.

The Parties have filed cross-motions for summary judgment. Plaintiff argues that Regence improperly denied coverage. Plaintiff's Motion for Summary Judgment, docket no. 14. Regence claims that coverage was properly denied under the terms of the Plan as "not medically necessary" because another form of radiation therapy provides equivalent treatment at a lower cost. Defendants' Motion for Summary Judgment, docket no. 25.

II. Standard of Review

The standard of review in an ERISA case in which benefits were denied is de novo, unless the plan confers discretion on the administrator. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989). The Parties agree that the Plan did not confer discretion on the administrator and that this Court reviews Regence's denial of coverage de novo. Plaintiff's Motion for Summary Judgment at 15-16; Opposition to Plaintiff's Motion for Summary Judgment at 17, docket no. 27.

The Court may grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).[1] The moving party bears the initial burden of informing the Court of the basis for summary judgment. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party makes an initial showing, the burden shifts to the opposing party to show that summary judgment is not warranted because a genuine issue of material fact exists. Id. at 324. A genuine issue of material fact exists only if the evidence is such that a reasonable trier of fact could resolve the

[1] Under de novo review, the Court typically considers only the evidence that was before the Plan administrator. See Mongeluzo v. Baxter Travenol Disability Benefit Plan, 46 F.3d 938, 943-44 (9th Cir. 1995). However, in the present case both Parties rely on extra-record evidence in the form of expert reports and declarations that are not included in the Administrative Record. The Parties appear to agree that this is appropriate. But in his Response brief, Plaintiff contends that Regence improperly relies on the previously undisclosed expert testimony of Richard Rainey, M.D., and moves to strike Dr. Rainey's undisclosed testimony. Response to Defendants' Motion for Summary Judgment at 1, docket no. 30. The Court DENIES the Motion to Strike the Declaration of Dr. Rainey and GRANTS the Plaintiff's alternative request for the Court to consider the responsive declaration of Dr. Rossi, filed as docket no. 31. Id. at 2-3. In addition, the Court has considered the second declaration of Dr. Rossi, docket no. 40, and the rebuttal declaration of Dr. Grimm, docket no. 42.

dispute in favor of the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). In reviewing the evidence, "the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." Reeves v. Sanderson Plumbing Prods. Inc., 530 U.S. 133, 150 (2000).

III. Burden of Proof

"Section 502 of ERISA entitles a participant or beneficiary of an ERISA-regulated plan to bring a civil action 'to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan.'" Chappel v. Lab. Corp. of Am., 232 F.3d 719, 724 (9th Cir. 2000) (quoting 29 U.S.C. § 1132(a)(1)(B)). When a district court reviews a plan administrator's decision to deny benefits under the de novo standard of review, the burden of proof is placed on the claimant to prove his entitlement to contractual benefits. Muniz v. AMEC Const. Mgmt, Inc., 623 F.3d 1290, 1294 (9th Cir. 2010) (citing Horton v. Reliance Standard Life Ins. Co., 141 F.3d 1038, 1040 (11th Cir. 1998); Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653, 658 (8th Cir. 1992)).[2]

Plaintiff, never-the-less, contends that Regence bears the burden to prove that proton therapy is not medically necessary. He contends that this is so because the Plan

[2] Other district courts in the Ninth Circuit have consistently held that the burden of proving entitlement to benefits is on the Plaintiff where a district court reviews a plan administrator's decision under the de novo standard of review. See, e.g., Schwartz v. Metro. Life Ins. Co., 463 F. Supp. 2d 971, 982 (D. Ariz. 2006) ("Plaintiff has the burden of proof to show that he was eligible for continued long term disability benefits based on the terms and conditions of the ERISA plan."); Sabatino v. Liberty Life Assurance Co. of Boston, 286 F. Supp. 2d 1222, 1232 (N.D. Cal. 2003) ("The Court concludes that Plaintiff must carry the burden to prove that she was disabled under the meaning of the plan."); Jordan v. Northrop Grumman Corp. Welfare Benefit Plan, 63 F. Supp. 2d 1145, 1155 (C.D. Cal. 1999) ("[T]he burden in making such a claim [for entitlement to benefits] is on Plaintiff.").

includes an exclusion for services that are "not medically necessary," and cites the general principle of insurance law that the insurer bears the burden of proving that an exclusion applies. Regence responds that Plaintiff bears the burden of proving that proton therapy is a medically necessary treatment for clinically localized prostate cancer because the coverage section of the plan includes the requirement that medical services must be "medically necessary" to be covered. To answer the question of whether the burden of proving medical necessity falls on the Plaintiff or the Defendant, the Court must determine whether "medical necessity" falls within the definition of coverage. The Court turns to the Plan language to make this determination.

The "Medical Benefits" section of the Plan states, in the introductory paragraph, that "Your coverage" pays for "Covered Services." AR at 542. A "Covered Service" is defined by the Plan as "a service, supply, treatment or accommodation that is listed in the benefits section of the Contract." Id. at 603. The introduction to the "Medical Benefits" section further provides:

> All covered benefits are subject to the limitations, exclusions and provisions of this plan. To be covered, medical services and supplies must be ***Medically Necessary*** for the treatment of an illness or injury (except for any covered preventative care). Also, a Provider practicing within the scope of his or her license must render the service. Please see the Definitions Section in the back of this Booklet for descriptions of ***Medically Necessary*** and of the kinds of Providers who deliver Covered Services.
>
> A Health Intervention may be medically indicated yet not a Covered Service under the Contract or otherwise be ***Medically Necessary***.

Id. at 542 (emphasis added).

The Plan also includes an exclusion for services that are "Not Medically Necessary." That provision excludes:

> Services and supplies that are not Medically Necessary for the treatment of an Illness or Injury, except for preventative care benefits specifically provided under the Contract.

Id. at 569.

The Plan defines "Medically Necessary or Medical Necessity" as follows:

> Health care services or supplies that a Physician or other health care Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an Illness, Injury, disease or its symptoms, and that are:
>
> - In accordance with generally accepted standards of medical practice;
> - Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's Illness, Injury or disease, and;
> - Not primarily for the convenience of the patient, Physician or other health care Provider, and ***not more costly than an alternative service or sequence of services or supply at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's Illness, Injury or disease***.

Id. at 605 (emphasis added).

Plaintiff argues that the Plan language and applicable case law demonstrate that the requirement of medical necessity is an exclusion that puts the burden of proof on the Defendant to show that coverage was properly denied. In support, Plaintiff cites three district court decisions from the Ninth Circuit where the court concluded that a defendant had the burden of proving that a policy exclusion applied. See Boldon v. Hamana Ins. Co., 466 F. Supp. 2d 1199, 1202 (D. Ariz. 2006); Sabatino v. Liberty Life Assurance Co. of Boston, 286 F. Supp. 2d 1222, 1232 (N.D. Cal. 2003); Gonzalez v. Cent. Elec. Co-op,

Inc., 2011 WL 39650, at *3 (D. Or., Jan. 6, 2011). The Court concludes that these cases are not controlling here. In Boldon and Sabatino, the district court reviewed the denial of benefits for abuse of discretion rather than de novo. In the third case, Gonzales, the Court also concluded that "it is the plaintiff's burden to show he falls under the provisions of the plans entitling him to benefits." Gonzalez, 2011 WL 39650, at *3.

The Ninth Circuit has not considered whether the requirement of medical necessity is a term of coverage or an exclusion under circumstances similar to this case where the term falls both within the coverage section of the plan and in the exclusions section. However, three other circuit courts have considered a similar question. In Farley v. Benefit Trust Life Ins. Co., the Eighth Circuit considered whether language in an insurance policy limiting coverage to treatment considered "medically necessary" was properly coverage language tied to the benefits section of the plan or an exclusion. 979 F.2d 653, 658 (8th Cir. 1992). In that case, the insurer had denied coverage for certain cancer treatment as not medically necessary because it was "investigational/ experimental." Id. After the insurer denied plaintiff's appeals, plaintiff filed suit under ERISA and the district court held a three day bench trial. Id. at 656. The trial court found that:

> The original policy had been amended to add provisions describing "medically necessary" treatment and limiting benefits only to treatment considered "medically necessary" under that description; that the description contained five criteria for "medically necessary" treatment; that the treatment given to [plaintiff] met three of those criteria; and that the treatment failed to meet two of those criteria.

Id. The trial court granted summary judgment to the insurer and dismissed the plaintiff's claim, concluding that the treatment was not "medically necessary" as required by the plan.

The plaintiff appealed, arguing that the trial court erred in concluding that he had the burden of proof on the question of whether the treatment was "medically necessary." The Eighth Circuit rejected the claimant's argument that the "medically necessary" language was an exclusion and that the insurer, not the policy holder, had the burden of proving the exclusion applied. Id. The Court reasoned:

> The exclusions section does state that "No Benefits are paid for . . . service or supplies not required for the Covered Condition," however, we construe this merely as a repetition of the benefits description as payable only for necessary (or as amended, medically necessary) expenses. . . . Accordingly, we agree that it was [the claimant's] burden to show that he was entitled to the "benefits . . . under the terms of his plan.

Id.

Reviewing the same plan as the Farley court, the Seventh Circuit also agreed that the burden of proving medical necessity rested with the plaintiff. Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1408 (1994). Similarly, the Second Circuit adopted the Farley Court's reasoning in Juliano v. Health Maintenance Organization of New Jersey, Inc., holding that the burden of proof in an ERISA case is on the plaintiff to establish the medical necessity of treatment where medical necessity is a prerequisite for entitlement to benefits. 221 F.3d 279, 287-88 (2nd Cir. 2000).

Moreover, the Ninth Circuit recently affirmed that where a trial court reviews a denial of benefits de novo, the burden of proof is placed on the claimant to prove his entitlement to contractual benefits. Muniz, 623 F.3d at 1294. In Muniz, the Court stated:

> As concluded by other circuit courts which have addressed the question, when the court reviews a plan administrator's decision under the de novo standard of review, the burden of proof is placed on the claimant.

Id. (citing Horton, 141 F.3d at 1040; Farley, 979 F.2d at 658). Thus, Muniz recognized that before a court addresses exclusionary language, the plaintiff bears the burden of showing that he is entitled to coverage under the plan language.

The Court concludes that the Plaintiff bears the burden of showing that proton therapy was a medically necessary treatment for his disease. First, the Ninth Circuit has stated unambiguously that where a district court reviews the denial of benefits de novo in an ERISA case, the claimant bears the burden of proving that coverage exists. Muniz, 623 F.3d at 1294. Second, to the extent that Plaintiff argues that Regence bears the burden of proof because the "medically necessary" language is included in a policy exclusion, the Court concludes that the reasoning in Farley is on point. The introduction to the "Medical Benefits" section of the Plan clearly provides that "[t]o be covered, medical services and supplies must be Medically Necessary for the treatment of an illness or injury." AR at 542. The Plan's later exclusion of "Services and supplies that are not Medically Necessary," id. at 569, should be construed merely as a repetition of the benefits description which states that benefits are payable only for medically necessary expenses. Farley, 979 F.2d at 658.

IV. Discussion

Regence argues that it is undisputed that proton therapy is more expensive than IMRT and that IMRT is at least as likely to produce equivalent therapeutic results as to the treatment of Plaintiff's disease. Plaintiff contends that IMRT is not an equivalent treatment to proton therapy in terms of therapeutic results and that Regence has not met its burden to demonstrate that proton therapy is more costly than IMRT.

1. Scientific Background

Before the Court analyzes the Parties' arguments, a review of the science of radiation therapy, and its use in the treatment of prostate cancer specifically, is appropriate. The biological effect of radiation on living cells varies depending on the level of radiation exposure. U.S. Nuclear Regulatory Commission Fact Sheet, "Biological Effects of Radiation" at 2 (Ex. C to Birk Decl., docket no. 17). High doses of radiation tend to kill cells, while low doses tend to damage or alter the genetic code (DNA) of cells. Id. at 3. Radiation therapy refers generally to medical uses of radiation, primarily in the treatment of cancer. Rossi Report at 17, docket no. 16. Because cancer cells are more susceptible to the effects of radiation than normal cells, the goal of radiation therapy for cancer treatment is to give enough radiation to the tumor to kill it without giving so much that irreversible damage occurs in the surrounding healthy tissue. Id.

Historically, radiation therapy has been delivered through x-rays (photons). Id. at 17-18. Due to the physical properties of photons, x-rays travel through the patient depositing radiation along the beam path to the site of the targeted cancer, and then out

through the other side of the patient's body. Id. at 18; see also Bradford Hoppe et al., "Proton Therapy for Prostate Cancer," 25 Oncology 7 (June 8, 2011). As a result, normal tissue is irradiated in the process of treating the cancer. Id. For this reason, research into new radiation therapy treatments is focused on allowing radiologists to more precisely target cancer cells, while sparing the surrounding healthy tissue. Rossi Report at 17.

Until the early 1990s, the standard of care for radiation therapy was 2-dimensional external beam x-ray radiation therapy, which allowed for a total dose of 67-70 Gy[3] of radiation to the target site. National Comprehensive Cancer Network Prostate Cancer Guidelines (2012) ("NCCN Guidelines"),[4] AR at 313. More recently, 3-dimensional planning techniques have been developed which allow higher doses of radiation to be administered to the cancer site, without similarly increasing the amount of radiation ("integral dose") to surrounding healthy tissue.[5] Id. The first generation of 3D radiation therapy technology, 3D-CRT, uses computer software to integrate CT images of the patient's anatomy and permit the radiologist to more accurately "conform" the high dose radiation to the exact shape of the prostate, thereby reducing the exposure to non-cancerous tissue. Id. at 313-14. Today, the most advanced form of x-ray radiation

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[3] The gray (symbol: Gy) is the "International System unit of absorbed dose, equal to the energy imparted by ionizing radiation as a mass of matter corresponding to 1 joule per kilogram." MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 926 (6th Ed. 2003)

[4] The National Comprehensive Cancer Network is an organization of 23 of the largest and best-known cancer centers in the United States. The NCCN produces practice guidelines that describe best practices for cancer care. See http://www.nccn.org/clinical.asp.

[5] The term "integral dose" is defined as the "total energy imparted to an irradiated body by an ionizing radiation." MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 1088 (6th Ed. 2003).

therapy available is intensity-modulated radiation therapy (IMRT), which uses computer, CT, and magnetic resonance imaging (MRI) images to allow for greater treatment accuracy ("conformance") and safer dose escalation (i.e. increases in the amount of radiation delivered to the targeted area). Id. at 314.

In addition to improvements in x-ray radiation therapy, newer technologies have introduced other modalities of radiation treatment. These include brachytherapy, in which a radioactive "seed" is implanted into the prostate tissue, id. at 315, and proton therapy, which is at the heart of this lawsuit. Proton therapy involves using beams of protons or helium ions to deliver radiation to the targeted area. Regence Medical Policy 49 "Charged Particle (Proton or Helium Ion) Radiation Therapy," AR at 81.

> In contrast to x-rays, protons have mass and thus do not travel an infinite distance; rather, they stop in tissue at a distance proportional to their acceleration. . . . Unlike x-rays . . . protons lose relatively little energy along the beam path until the end of their range, at which point they lose the majority of their energy, producing a characteristic sharp peak in radiation energy deposition known as the Bragg peak. Thus, a typical proton beam disperses a low constant dose of radiation along the entrance path of the beam, a high uniform dose throughout the range of the [spread-out Bragg peak], and no exit dose.

Bradford Hoppe et al., "Proton Therapy for Prostate Cancer," 25 Oncology 7 (June 8, 2011). As a result, proton therapy "may be used to reach deeply-located tumors with less damage to surrounding tissues." NCCN Guidelines, AR at 315.

Radiation therapy is one of the principal treatment options for clinically localized prostate cancer. NCCN Guidelines, AR at 313. However, the NCCN Guidelines do not recommend proton therapy for routine use in the treatment of early stage prostate cancer at this time "since clinical trials have not yet yielded data that demonstrates superiority

to, or equivalence of, proton beam and conventional external beam for treatment of prostate cancer." Id. at 315. This recommendation is consistent with a 2008 review by the Agency for Healthcare Research and Quality (AHRQ), which concluded that while the rates of clinical outcomes and toxicity after proton therapy may be comparable with conformal radiation, "[t]here was no direct evidence that proton EBRT results in better overall or disease-free survival than other therapies." Rainey Decl. at 18-19 (docket no. 22-2). As a result of the current uncertainty concerning the comparative value of proton therapy in the treatment of prostate cancer, the National Cancer Institute, the Institute of Medicine, the AHRQ, the American College of Radiology, and the Centers for Medicare and Medicaid Services have all called for randomized studies comparing proton therapy with x-ray radiation therapy. Lawrence et al., "Protons for Prostate Cancer, the Dream Versus the Reality," 105(1) J. Nat'l Cancer Inst. 8 (January 2, 2013) (docket no. 19-4); American College of Radiology (ACR) Appropriateness Criteria, AR at 113 (concluding "there are only limited data comparing proton beam therapy to other methods of irradiation or to radical prostatectomy for treating stage T1 and T2 prostate cancer. Further studies are needed to clearly define its role in such treatment.").

Plaintiff claims that despite the lack of randomized clinical trials comparing proton therapy to other forms of radiation therapy for treatment of prostate cancer, the available evidence from observational studies combined with the theoretical advantages of proton therapy show that it is superior to other radiation techniques for the treatment of prostate cancer.

2. Cost Comparison

In Plaintiff's Motion for Summary Judgment, he concedes that proton therapy is more costly than IMRT or other forms of x-ray radiation therapy. Plaintiff's Motion for Summary Judgment at 8 ("There is no dispute that proton therapy is more costly than x-ray therapy.") However, he backtracks from this admission in his Response to the Defendants' Motion for Summary Judgment. There, Plaintiff argues that Regence must prove that proton therapy is more costly than x-ray therapy and claims that "Regence has not offered evidence from which the Court could conclude that proton therapy would be necessarily more costly than x-ray therapy in Mr. Baxter's case." Plaintiff's Response to Defendants' Motion for Summary Judgment at 6-7. Plaintiff argues that the only evidence proffered by Regence is that proton therapy facilities are expensive and the testimony of Dr. Rainey that Regence analyzed and compared the cost of proton therapy with the cost of IMRT prior to revising its Policy 49. He contends that this evidence is insufficient because it does not involve a comparison of the cost of treatment in Mr. Baxter's case. Id. The Court rejects Plaintiff's argument for two reasons.

First, the Court exercises its discretion and treats Plaintiff's admission in his motion for summary judgment as a binding judicial admission. Gospel Missions of Am. v. City of L.A., 328 F.3d 548, 557 (9th Cir. 2003) (holding courts "have discretion to consider a statement made in briefs to be a judicial admission . . . binding on . . . the trial court."); see also Purgess v. Sharrock, 33 F.3d 134, 144 (2d Cir. 1994) ("A court can appropriately treat statements in briefs as binding judicial admissions of fact."). Here, Plaintiff unambiguously conceded in his summary judgment motion that proton therapy

is more costly than x-ray therapy. Plaintiff should not be permitted to abandon this argument and take a different position in later-filed briefing.

Second, Plaintiff's argument is premised on the misconception that the burden of proof in these cross-motions for summary judgment lies with the Defendant. Because the requirement of "medical necessity" is contained in the coverage section of the Plan, Plaintiff bears the burden of showing proton therapy is "not more costly than an alternative service or sequence of services or supply at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's Illness, Injury or disease." AR at 605. As such, Plaintiff is required to prove that the cost of proton therapy is not more costly than IMRT. He has proffered no credible evidence to support this contention, other than the statement of Dr. Rossi in his rebuttal Declaration that "in some cases" he can treat cancer more economically with proton therapy than with IMRT. Rossi Rebuttal Decl. at 3, docket no. 31. However, Dr. Rossi concedes that it is "impossible to tell" whether proton therapy was more expensive in the Plaintiff's case. Rossi Decl. at 3, docket 31. Plaintiff has not met his burden to show that it would have been more costly to treat his cancer with IMRT than with proton therapy.

Accordingly, the Court concludes that Plaintiff has failed to raise a material issue of fact on whether proton therapy is more costly than IMRT.

3. <u>Therapeutic Equivalence</u>

The second issue before the Court is whether proton therapy is equivalent or "superior" to IMRT. The Plan provides that a treatment is "medically necessary" if "a

Physician or other health care Provider, exercising prudent clinical judgment, would provide [it] to a patient for the purpose of . . . treating an Illness, Injury, disease or its symptoms," and that the treatment is:

> not more costly than an alternative service or sequence of services or supply at ***least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment*** of that patient's Illness, Injury or disease.

Id. at 605 (emphasis added). Because the Court concludes that proton therapy is more costly than IMRT, in order to prevail on these cross motions for summary judgment, Plaintiff must demonstrate that proton therapy and IMRT are not equivalent treatments. In other words, Plaintiff must demonstrate that proton therapy is a superior treatment to IMRT.

Plaintiff argues that proton therapy is superior to IMRT because it results in fewer and less severe side-effects, including fewer secondary cancers. Whether this position is correct will dictate the result in this case. The Parties' appear to agree that the available medical evidence suggests that IMRT and proton therapy are equivalent in terms of their ability to cure/control prostate cancer (i.e. the available evidence supports the conclusion that clinical outcomes are equivalent).[6] The Parties' disagreement centers on the severity of the side-effects that patients experience as a result of treatment.

[6] See Rainey Decl. at 2-3, docket no. 22 (stating that Regence's decision to stop covering proton therapy as a treatment for prostate cancer, after previously covering the treatment, was not based on a change in the medical evidence concerning clinical efficacy of proton therapy, but rather on the fact that proton therapy is more expensive than IMRT).

Plaintiff argues that the side effects associated with proton therapy are less severe than the side effects associate with x-ray therapy because proton therapy results in less radiation to healthy tissue than x-ray therapy. Plaintiff's argument can be broken down into two components. First, the reduction in radiation to healthy tissue compared to IMRT results in a reduced risk of developing secondary cancers over time. Second, proton therapy results in fewer and less severe side-effects of treatment, including GI (bowel), urinary, and potency (sexual dysfunction) side-effects. Defendants disagree with Plaintiff's interpretation of the existing body of scientific research and contend that there is no statistically significant evidence in the form of randomized clinical trials to support Plaintiff's arguments.

A. Risk of Secondary Cancers from Radiation Exposure

Plaintiff contends that due to the physical properties of protons, healthy tissue in the beam path is exposed to less radiation compared to x-ray radiation therapy. He argues based on several studies that use mathematical models to predict the risk of secondary cancers from radiation exposure that proton therapy therefore will result in fewer secondary cancers compared to x-ray radiation therapy. Rossi Report at 20-23. Defendants contend that this argument is incorrect and misleading. Opposition to Plaintiff's Motion for Summary Judgment at 5. They argue that the theory that proton therapy results in fewer secondary cancers compared to IMRT is not substantiated by randomized clinical trials. Defendants' expert, Dr. Beer is also critical of the studies cited by Plaintiff because they are based on mathematical models of treatment rather than imagery of radiation deposition in an actual patient. Beer Decl. at 11, docket no. 21.

From the Court's review of the record in this case, it appears that treating prostate cancer with proton therapy may result in deposition of less radiation to certain healthy parts of a patient's anatomy compared to x-ray radiation. However, proton therapy may also deposit more radiation to other portions of the patient's anatomy than IMRT. See, e.g., Grimm Declaration at ¶¶ 10, 13, docket no. 42; Alexei et al., "Radiotherapy Treatment of Early Stage Prostate Cancer with IMRT and Protons: A Treatment Planning Comparison," 69 Int. J. Radiation Oncology Biol. Phys. 444 (2007) (IMRT resulted in less radiation to bladder in the range over 70 Gy/CGE, while proton therapy resulted in less radiation to rectum and bladder in the range below 30 Gy/CGE). However, the question before the Court is not whether proton therapy deposits more or less radiation to any particular location, but whether there is evidence that the proton therapy is superior to IMRT. The Court concludes that the Defendants are correct that this question must be answered based on clinical outcomes of patient treatment. As a result, mathematical models that predict that proton therapy will result in less radiation to certain parts of a patient's anatomy and thus, fewer secondary cancers, are insufficient to create a material issue of fact at trial.

Plaintiff argues that in his individual case the risk of secondary malignancy is especially important because of his young age (51 at the time of diagnosis). He contends that his life expectancy is much longer than the average prostate cancer patient and that therefore, his risk of developing a secondary radiation-induced tumor is of greater concern. This argument supports Plaintiff's personal choice to pursue proton therapy. However, it does not create a material issue of fact for trial on the issue of whether proton

therapy results in fewer secondary malignancies. The Plaintiff has not proffered any evidence to the Court to support his theory that proton therapy results in fewer incidents of secondary cancer than IMRT at the same clinical dose. The Court concludes that at this time there is insufficient evidence to present a material issue of fact at trial whether there is a statistically significant reduction in the risk of developing a secondary cancer as a result of radiation therapy with proton therapy versus x-ray therapy.[7]

B. Proton Radiation Oncology Group (PROG) 95-09 Study

The primary study relied upon by Plaintiff to support his position that proton therapy results in fewer side-effects than IMRT is the PROG 95-05 study. See Plaintiff's Motion for Summary Judgment at 10-11. That study was a randomized trial designed to measure freedom from biochemical failure (recurrence) at five years in two control groups with clinically localized prostate cancer. The first group received a total dose of radiation of 70.2 Gy comprised of 50.4 Gy of standard conformal (x-ray) radiation and a "boost" of 19.8 Gy of radiation delivered using proton therapy. Zietman et al., "Comparison of Conventional-Dose v. High-Dose Conformal Radiation Therapy in Clinically Localized Adenocarcinoma of the Prostate," 294 JAMA 1233, 1234 (September 14, 2005) (hereinafter "Zietman"). The second group received 50.4 Gy of x-ray radiation and a boost of 28.8 Gy of radiation delivered using proton therapy for a total

[7] The Court notes that with the increasing use of proton therapy for the treatment of prostate cancer, additional studies may one day prove that there is a statistically significant reduction in the risk of developing a secondary cancer as a result of radiation therapy with proton therapy versus x-ray therapy. However, this Court cannot divine the future and must make a decision based upon the medical evidence before the Court at this time.

dose of 79.7 Gy. Id. The study was designed to test whether increasing the total delivered radiation dose to the cancer could increase tumor/disease control. Id.

In addition to measuring the impact on cancer control, the study also tracked the incidence and severity of GI (gastrointestinal) and GU (genitourinary) side-effects between the two trial groups, using the physician reported Radiation Therapy Oncology Group (RTOG) rating system in which side-effects are measured on a scale from grade 1 (least severe) to grade 5 (most severe). Id. at 1237-38. The study concluded that men with clinically localized prostate cancer who are treated with high-dose radiation therapy are more likely to be free from locally persistent disease 5 years post-treatment than men treated with conventional-dose radiation. Id. at 1238. The researchers also concluded that this outcome could be achieved with only a small, two percent increase in grade 2 rectal side-effects and no statistically significant increase in GU side-effects. Id. However, the researchers specifically indicated that although the trial "validates the use of proton-beam therapy, it did not test whether this modality is more or less efficacious than other less expensive and more commonly available conformal techniques or, for that matter, than brachytherapy or surgery." Id. at 1239.

A second, follow-up study was conducted using the same trial cohort in 2009 at a median of 9.4 years after the completion of treatment. Talcott et al., "Patient-Reported Long-Term Outcomes After Conventional and High-Dose Combined Proton and Photon Radiation for Early Prostate Cancer" 303 JAMA 1046 (March 17, 2010) (hereinafter "Talcott"). The follow-up study was designed to measure patient-reported incidents of sexual function, urinary and bowel complications of treatment, and quality of life. Id. at

1047. The study reported "little evidence of added urinary, bowel, or sexual dysfunction in the high-dose treatment group. Id. at 1049. As a result, the researchers concluded that "radiation at the higher doses now commonly used were not associated with increased patient-reported, long-term, treatment-related urinary, bowel, or sexual dysfunction or related quality of life outcomes." Id. at 1050. The authors offer six possible explanations for the study results. Id. at 1050-51. Of these possible explanations, the Plaintiff focuses on the first—that the increased radiation dose is not correlated to increases in long-term side-effects because the technique used to administer the radiation boost (proton beam) minimized exposure to nearby critical tissue. Id. at 1050-51.

The Parties each argue that the PROG 95-09 study supports their position. The Defendants contend that the PROG 95-09 study has no bearing on the issue of whether proton therapy is more or less efficacious than IMRT. Defendants point out that the study was not designed to and did not test whether proton therapy is more or less efficacious than other modalities of radiation treatment. Zietman at 1239. Defendants also argue that the study shows exactly what would be expected with any increase in radiation, regardless of modality—that secondary side-effects increased slightly with increases in the total therapeutic dose of radiation to the target cancer.

Plaintiff argues that the PROG 95-09 study supports his argument that proton therapy is superior to IMRT because it would have been impossible to apply the increased doses of radiation to the "high dose" arm of the study with conventional x-ray therapy without increasing the side-effects experienced by patients. He claims that if the doses of radiation delivered in the study had been provided with x-ray therapy alone it

would have done an intolerable level of damage to the surrounding tissue. Plaintiff's Response to Defendants' Motion for Summary Judgment at 9. Plaintiff also argues that the fact that there was not a corresponding increase in "grade 3" side-effects with the dose escalation supports his argument that proton therapy is a superior form of radiation therapy. Id. Plaintiff focuses specifically on the fact that "grade 3" side effects did not increase, even though "grade 2" side effects saw a moderate increase with increased dosage. Rossi Decl. at 6, docket no. 31. He contends that this is significant because "multiple published randomized x-ray based dose-escalation trials show . . . increase in Grade 3 side-effects." Id.[8]

The Court rejects Plaintiff's argument that the PROG 95-09 study demonstrates that proton therapy is superior to IMRT. As the authors recognize, the study validates the use of proton therapy for the treatment of prostate cancer. Id. But due to the fact that each patient received both conformal radiation and proton beam therapy, it cannot reasonably be said that the study demonstrates that proton therapy is superior to conformal radiation. Moreover, to the extent the study shows that proton therapy can be used to increase (or escalate) the total dose of radiation without significantly increasing related side-effects more successfully than x-ray therapy, this is irrelevant in the current case. Plaintiff did not request authorization for proton beam therapy at a higher therapeutic dose than what was available with IMRT. Moreover, Defendants point out that the standard dose of radiation currently delivered with IMRT is consistent with the

[8] Dr. Rossi does not identify any of the studies that he relies upon for this proposition.

"escalation dose" in the PROG 95-09 study. Grimm Decl. at 3, docket no. 28; Beer Decl. at 6, docket no. 29.

In short, the PROG 95-09 study demonstrates that proton therapy may be used to effectively treat prostate cancer. It does not, however, support the proposition that proton therapy is superior to IMRT in either clinical efficacy (i.e. ability to treat/cure cancer) or the ability to reduce the side-effects of treatment.

C. Lack of Randomized Trials Comparing IMRT to Proton Therapy

Plaintiff argues that the fact that there are no controlled randomized studies that compare proton therapy to IMRT, brachytherapy, or robotic surgery should not be dispositive because Regence admits that it covers all of these therapies despite the lack of controlled randomized studies proving their superiority compared to other modalities of treatment. See Regence IMRT Policy (Ex. 3 to Little Decl., docket no. 19). Rather, Regence admits that it covers these treatments because the available non-randomized data demonstrate reduced rates of toxicity compared to older generation CRT radiation therapy. Id.; see also Defendants' Motion for Summary Judgment at 7-8. Plaintiff argues that the same type of non-randomized observational studies support his argument that proton therapy results in fewer and less-severe side effects compared to IMRT.

Plaintiff's argument is not persuasive. Although the parties characterize the existing non-randomized observational studies comparing IMRT to proton therapy in different ways, the Court concludes that the record demonstrates that IMRT and proton therapy provide equivalent cancer treatment with comparable side-effects. While Plaintiff points to observational studies demonstrating that proton therapy may slightly

reduce certain side-effects in some situations, it appears that it is just as likely to increase other side effects. See, e.g., Sheets et al., "Intensity-Modulated Radiation Therapy, Proton Therapy, or Conformal Radiation Therapy and Morbidity and Disease Control in Localized Prostate Cancer," 307(15) JAMA 1611 (April 18, 2012) (concluding that proton therapy patients had higher levels of gastrointestinal side-effects than IMRT patients); Yu et al., "Proton versus intensity-modulated radiotherapy for prostate cancer: patterns of care and early toxicity," 105(1) J. Nat'l Cancer Inst. 25-32 (Jan 2, 2013) ("High dose proton radiation was associated with small increases in bowel dysfunction and incontinence, with more pronounced changes in sexual dysfunction."). The inconsistencies in the current observational studies comparing proton therapy with other modalities of treatment for prostate cancer are consistent with the NCCN's conclusion that the use of proton therapy is not recommend for routine use in the treatment of early stage prostate cancer at this time "since clinical trials have not yet yielded data that demonstrates superiority to, or equivalence of, proton beam and conventional external beam for treatment of prostate cancer." Id. at 315.

Based on the applicable standard of review, Plaintiff has not met his burden to show that there is a genuine issue of material fact whether proton therapy is superior to IMRT. The current non-randomized observational studies demonstrate that proton therapy provides equivalent treatment to IMRT in terms of cancer control and side-effects. Plaintiff focuses on studies involving mathematical modeling that show that the long-term risk of developing a secondary malignancy may be higher with proton therapy. Fontenot, et al., "Risk of secondary malignant neoplasms from proton therapy and

intensity-modulated x-ray therapy for early-stage prostate cancer," 74(2) Int. J. Radiation Oncology Biol. Phys. 616 (2009) (model showed that proton therapy reduced risk of developing secondary cancer as compared to IMRT by 26-39%). Defendants focus on comparative studies that show that other side-effects, including gastrointestinal side-effects may be slightly more severe with proton therapy. See Sheets at 1611 (concluding that proton therapy patients had higher levels of gastrointestinal side-effects than IMRT patients). No study cited by either party provides statistically significant evidence that one therapy is superior to the other.

4. Breach of Fiduciary Duty, 29 U.S.C. § 1132(a)(3)

In addition to bringing a claim for coverage under ERISA, 29 U.S.C. § 1132(a)(1)(B), Plaintiff seeks specific performance under the Plan pursuant to 29 U.S.C. § 1132(a)(3). Section 1132(a)(3) provides for a claim

> by a participant, beneficiary, or fiduciary (A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan.

However, relief under ERISA's "catchall" provision is prohibited where an action under other provisions of Section 1132 provide an adequate remedy. Varity v. Howe, 516 U.S. 489, 512 (1996). The Ninth Circuit has explained that equitable relief under Section 1132(a)(3) is not appropriate where an action under Section 1132(a)(1) provides an adequate remedy. Forsyth v. Hamana, Inc., 114 F.3d 1467, 1475 (9th Cir. 1997).

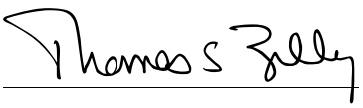
Defendant moves to dismiss Plaintiff's claim under Section 1132(a)(3) because he has not demonstrated that Section 1132(a)(1)(B) does not provide an adequate remedy in

this action. Plaintiff did not respond to this argument and the Court concludes that Defendant is correct and Plaintiff's Section 1132(a)(3) claim is dismissed.

V. Conclusion

The Court GRANTS Defendants' motion for summary judgment, docket no. 18, and DENIES Plaintiff's motion for summary judgment, docket no. 14. Plaintiff has not met his burden to prove that proton therapy was covered under the relevant policy language. The Clerk is directed to enter Judgment in favor of the Defendants, dismissing Plaintiff's Complaint with prejudice and with costs.

Dated this 23rd day of July, 2013.



THOMAS S. ZILLY
United States District Judge